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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,375	12/12/2005	Takao Suzuki	10873.1839USWO	3824
53148 7590 10/09/2007 HAMRE, SCHUMANN, MUELLER & LARSON P.C. P.O. BOX 2902-0902 MINNEAPOLIS, MN 55402			EXAMINER FERNANDEZ, KATHERINE L	
			ART UNIT 3768	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/560,375	Applicant(s) SUZUKI ET AL.	
	Examiner Katherine L. Fernandez	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

1. Applicant's arguments filed July 6, 2007 have been fully considered but they are not persuasive.
2. After further consideration of the applicant's arguments on claims 1-9, examiner respectfully disagrees.

With regards to claim 1, applicant argues that Von Behren fails to disclose a control means that allows the tomographic image to be renewed in an arbitrary cycle, displayed by the display means, and stored in the memory means, while allowing the tissue characteristic image to be renewed in a cycle different from the cycle for the tomographic image, as required by claim 1. Examiner would like to point out that Von Behren disclose that their ultrasonic imaging system comprises of a "control means for controlling transmission and reception of ultrasound by the transducer and thereby for controlling repeated scanning of a region of interest (ROI) of a body with ultrasound generated by the transducer and for acquiring a first and second set of intensity values, each intensity value representing an imaging property of a respective portion of the ROI" (column 17, lines 61-67). Examiner would also like to point out that Von Behren discloses that the tissue characteristic images (i.e. elasticity images) are calculated from the tomographic images (i.e. intensity images), thereby implicating that the tomographic images are renewed in an arbitrary cycle different from the cycle for the tissue characteristic image (column 7, lines 51-65). Further, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from

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the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Therefore, with regards to claims 1-9, examiner maintains the previous office action dated April 10, 2007.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Von Behren et al. (U.S. Patent No. 6,558,324).

Regarding claim 1, Von Behren et al. disclose a diagnostic ultrasonic imaging method and system, in particular to the display of ultrasonic imaging data relating to the elastic properties (a tissue characteristic) of scanned tissue (column 1, lines 12-15). Their system includes a transducer (140) that serves to transmit and receive an ultrasonic wave with respect to a subject (column 4, lines 51-67 and column 5, lines 18-35). The apparatus also includes a processing unit (120) as well as a scan converter (122) that generate a 2D B-mode image for display (column 5, lines 36-63). The processing unit further contains elasticity estimation (125) and displacement estimation (124) software modules that create the tissue characteristic images (column 9, lines 31-

57). Von Behren further disclose that their system includes a memory (170) that stores the tomographic image (172 and 173), as well as the tissue characteristic image (174 and 175) (column 6, lines 31-48 and column 9, lines 31-45). An overlay module (131) within the processing unit combines the tomographic image with the strain image into a single displayed image (column 14, lines 10-22). The system includes a display (180) that can display the tomographic image as well as the tissue characteristic image (column 3, lines 6-33). A control circuit (138) controls the transmission and reception by the transducer, thereby controlling repeated scanning of a region of interest (column 17, lines 61-67). See Figure 1. The elasticity values are calculated as a function of differences between corresponding intensity values in the first and second sets of intensity values collected, which indicates that the B-mode images (i.e. tomographic images) are collected, displayed, and stored in the memory in a different cycle from when the tissue characteristic images are generated, displayed, and stored in the memory (column 3, lines 6-17). Further, Von Behren disclose that an embodiment of their invention in which the user can select a particular frame for display, indicating that one of the tissue characteristic images that was acquired previously and one of the tomographic images in synchronization with the tissue characteristic image can be read out from the memory and displayed (column 3, lines 34-43; column 15, lines 1-5).

Regarding claim 6, Von Behren et al. disclose that a related waveform (i.e. the average displacement) that contains information corresponding to at least one of the tomographic image and the tissue characteristic image to be displayed on a display screen of the display means in such a manner as to be combined with the tomographic

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image and the tissue characteristic image (column 15, lines 37-65, See Figure 6). They also disclose that the embodiment discussed above would be most useful in cine mode, where many frames are stored for later analysis (column 16, lines 53-59). Further, they disclose that a marker (612) highlights a portion of the related waveform and can be used to identify which frame is currently being displayed, as well as what its corresponding guide parameter is (column 15, lines 57-65, See Figure 6).

Regarding claim 8, the tissue characteristic image is an image representing a strain (column 14, lines 2-23).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Behren et al. in view of Varghese et al. (U.S. Patent No. 6,749,571), and further in view of Selzer et al. (U.S. Patent No. 6,979,294).

Von Behren et al. disclose that their system can display at least the tomographic image (i.e, gray-scale B-mode image) as well as the tomographic image on which the tissue characteristic image (i.e. elasticity frame) is superimposed (column 3, lines 6-17; column 14, lines 23-38). They also disclose that the images may be displayed during the operation of the ultrasonic wave transmission/reception (i.e. real-time display)

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(column 15, lines 1-5). As discussed above, the images may be generated and displayed in cine mode by operating on an entire stored sequence of B-mode and strain image frames, and the user may select different frames to display (column 15, lines 1-5; column 16, lines 19-30).

However, Von Behren et al. do not disclose that the display means is divided into a first display region and a second display region, that at least the tomographic image is displayed in the first display region, and the superimposed images on the second display region, and that during the operation of ultrasonic wave transmission/reception, the tomographic image is displayed at least in the first display region, while allowing the tissue characteristic image to be displayed in the second display region, nor do they disclose that one of the tomographic images that is in synchronization with the tissue characteristic image is displayed in the second display region during this time. Further, they do not disclose that during suspension of the ultrasonic wave transmission/reception, the tissue characteristic image and one of the tomographic images that is in synchronization with the tissue characteristic image can be displayed at least in the second display region of the display means, nor that during this time one of the tomographic images that is in synchronization with the tissue characteristic image is displayed in the first region. They also do not disclose that during the suspension of ultrasonic wave transmission/reception, the tissue characteristic image that is obtained based on a time period in which the tomographic image displayed in the first display region is included and the tomographic image that is in synchronization with the tissue characteristic image are displayed superimposedly in the second display region.

Varghese et al. disclose a method and apparatus for producing elastographic images of the heart to detect cardiac disease. They disclose that their method of displaying images involves displaying a conventional B-mode image (38) next to an elastographic image (72) (column 5, lines 57-65). The images may be updated in real time and oriented to show the same region of the heart tissue (column 5, lines 63-65). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Von Behren et al. to divide the display means into two regions, where in one display region the tomographic image is displayed, and the tissue characteristic image, in sync with the tomographic image, is displayed in the second display region. The motivation for doing so would have been to simplify navigating about the tissue characteristic image by providing a visual display that allows the user to compare the tomographic image with the tissue characteristic image (column 2, lines 23-37).

However, Von Behren et al. in view of Varghese et al. do not specifically disclose that the superimposed images (with the tomographic images and tissue characteristic images simultaneously displayed) are displayed in either the first or second display region as discussed in the instant claims 2-4.

Selzer et al. disclose a standardized method for obtaining an accurate and reproducible vascular characteristic measurement comprising of performing an ultrasonographic examination of vascular structures and capturing ultrasonographic images under a standardized procedure (column 3, lines 39-43). They disclose that a split-screen display is used in which an arterial ultrasound image from an earlier

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examination is displayed on one half of the screen while a real-time "live" ultrasound image from a current examination is displayed next to the earlier image on the other half of the screen (column 6, lines 51-60). The arterial ultrasound image from an earlier examination is retrieved from memory (column 5, lines 24-30). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Von Behren et al. in view of Varghese et al. to have displayed the images stored in memory (i.e. the superimposed images, the tomographic images, the tissue characteristic images) in either the first or second display regions. The motivation for doing so would have been to allow for visual comparison between the images, as taught by Selzer et al. (column 3, lines 44-56).

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Von Behren et al. in view of Nightingale et al. (U.S. Patent No. 6,371,912).

Von Behren et al. do not specifically disclose that the tissue characteristic image is an elastic modulus image. Nightingale et al. disclose an ultrasound method and apparatus for the identification and characterization of regions of altered stiffness in a target media (column 1, lines 19-21). They disclose that their invention creates an image of varying stiffness (i.e. increased or decreased elastic modulus) (column 2, lines 52-57; column 4, lines 32-37). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Von Behren et al. to create an elastic modulus image. The motivation for doing so would have been to aid in the early detection of breast cancer, as taught by Nightingale et al. (column 1, lines 23-34).

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8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Von Behren et al. in view of Seward (U.S. Patent No. 6,398,736).

Von Behren et al. do not disclose that the tissue characteristic image is an image representing a viscosity. Seward discloses a catheter apparatus for ultrasonic parametric imaging a visible fourth-dimensional or a non-visible higher-dimensional events in an underfluid environment (column 4, lines 8-42). Seward discloses that ultrasound is used to image viscosity (column 14, lines 12-27). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Von Behren et al. to create a viscosity image. The motivation for doing so would have been to provide information about the physiology of the tissue (column 1, lines 33-47).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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